PCT/GB 98/03073

The Patent Office

09/529210

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP9 1RH

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed Andrew Gersey

Dated 11 November 1998

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Patents Form 1/77

The Patent Office

1/77

310EC97 E327596-1 002*73
P01/7700 25.00 - 9727441.9

Request for grant of a patent

THE PATENT OFFICE
F
31 DEC 1997
RECEIVED BY POST

The Patent Office
Cardiff Road
Newport
Gwent NP9 1RH

1 Your reference MRH/P15367

31 DEC 1997

2 Patent application number **9727441.9**

3 Full name, address and postcode of the applicant

Virulite Limited
PO Box 210
Darlington
DL3 9GZ

Patents ADP number

State of incorporation 7305531001

4 Title of the invention

Treatment of Diseases

5 Name of agent **HARRISON GODDARD FOOTE**

Address for service

Belmont House
20 Wood Lane
LEEDS
LS6 2AE

Patents ADP number **14571001** 14571003

6 Priority applications

Country	Priority App No	Date of Filing
GB	**9721506.5**	**10 October 1997**

7 Parent application (eg Divisional)

Earlier Application No	Date of Filing

8 Statement of Inventorship Needed?

9 Number of sheets for any of the following (not counting copies of same document)

Continuation sheets of this form	
Description	13
Claims	-
Abstract	-
Drawings	15

10 Number of other documents attached

Priority documents	
Translations of priority documents	
P7/77	
P9/77	
P10/77	
Other documents	

11 I/We request the grant of a patent on the basis of this application.

Signature Harrison Goddard Foote 30 December 1997

12 Name and daytime telephone number of person to contact in the United Kingdom

Dr Michael R Harrison
0113 225 8350

TREATMENT OF DISEASES

This invention relates to the treatment of diseases and, more particularly, to the use of light to cure or alleviate a variety of diseases including infectious diseases and pathological processes including those caused by viruses and bacteria.

By way of example, reference will be made hereinafter to diseases caused by the herpes virus which is known to be responsible for a number of common ailments including corneal dendritic ulcers, genital herpes, herpes labialis (cold sores), herpes zoster (shingles) and herpes stomatitis. These infections tend to be recurrent and are not cured by existing, medically accepted treatments.

Current medically accepted methods of treating infections caused by the herpes virus are chemotherapeutic agents which are applied topically, injected or taken orally. Such treatment can often deal with the immediate infection but does not prevent a recurrence of the infection at a later date after the treatment has ceased.

It has been known for several decades that the use of light can give a positive therapeutic effect in the treatment of a wide spectrum of diseases. In the 1960's the use of narrow wavelength light was investigated in *in vivo/in vitro* experiments. It was found that light of wavelength greater than 440nm did not work. Further investigations were carried out with light having a wavelength of from 300 to 350nm (uv light) but it was found that infection was promoted rather than eliminated and the research work ceased.

It has now been surprisingly established that low intensity light of small bandwidth is effective in the treatment of infectious diseases and other conditions, including the alleviation of pain.

According to the present invention there is provided a light surgery system comprising means for producing low intensity, narrow bandwith light and means for

directing said light to a part of a human or animal body which is the target site for treatment.

Preferably the wavelength of the light is at least 950nm. A particularly preferred wavelength is at or about 1072nm. Preferably the wavelength of the light is no greater than about 3000nm.

The present invention also provides a method of treatment of an animal subject, including a human being, the method comprising applying to a site of pathology low intensity, narrow bandwidth light.

The use of restricted bandwidth light can enhance the immune system as a result of which the body is able to combat infections, such as the herpes virus. Accordingly, the present invention also provides a method of enhancing the immune system of an animal subject, including a human being, the method comprising applying to the animal subject low intensity, narrow bandwidth light.

Although reference has been made to infections caused by the herpes virus, the present invention is not limited to such infections. It is applicable to other infections caused by all viruses including HIV, common cold and influenza viruses.

The light may be directed to the target site either continuously or in a switched (pulsed) manner. Switching enables power conservation and facilities much higher peak power output, thereby improving clinical response.

Preferably, a light surgery system according to the present invention also includes means for reducing the amount of ambient light which impinges on the site of infection. The presence of ultraviolet light and violet light as in sunlight exacerbates herpetic conditions and it is preferred to exclude wavelengths below 400nm. More preferably, wavelengths below 500nm are excluded.

Preferably the system further includes means for fixing the intensity of the light within a pre-determined range. The optical output may be monitored with a visible display indicating correct function of the device both for intensity and wavelength.

Preferably the system includes means for controlling the duration of the application of the light. Accordingly, the present invention is concerned with the use of light having a wavelength in the range from visible to infra red and applied at a low intensity such that no thermal damage is caused to any human or animal tissues.

In the case where the system is to be used in such a way that light will be caused to enter the eye, it is preferred that the power density does not exceed 100 milliwatts per square centimetre. Otherwise, the power density may be higher and can suitably be delivered in pulsed form, thereby obtaining several watts of momentary power output, allowing good penetration of tissue and substantial systemic effect.

The light producing means are preferably solid state light emitting devices, more preferably solid state light emitting diodes or gas discharge devices. The light from such devices can be electrically operated or the light can be delivered to an applicator via a fibre-optic delivery system.

Preferably, the light emitter includes a PN junction arranged to emit light with a wavelength at or about 1072nm. A single light diode assembly may include a plurality of orientated junctions.

Infrared emitting diodes may be arranged not only to emit light at a specific frequency but also to emit a high intensity divergent beam.

A gas discharge device may include a mixture of gases which will give an output at the desired wavelength, for instance, 1072um.

Another preferred light producing means is a laser diode device, an example being a laser diode emitting light at a frequency of 1064mn. Such a light emitting means is of low power intensity having a divergent beam and not giving rise to thermal damage. It may be used to treat many conditions, including pain relief.

Preferably, the area to be treated is irradiated so that the affected tissue receives (after reflection and transmission have been accounted for) at least 500 millijoules of radiant energy per square centimetre. A factor here is the period of irradiation and, preferably, the period should be at least a specified minimum.

Embodiments of the invention will now be described, by way of examples only, and with reference to the accompanying drawings, in which:-

Figures 1 to 4 are a view with cover removed, side view, under view and front view respectively of a first embodiment in accordance with the present invention;

Figures 5 to 7 are a side view, section on AA (Figure 5) and top view of a second embodiment in accordance with the present invention;

Figures 8, 9 and 10 are a front view, top view and under view of a third embodiment in accordance with the present invention;

Figures 11, 12 and 13 are a back view, top view and a side view of a fourth embodiment of the present invention;

Figures 14 and 15 are a side view and a view from the right (as seen in Figure 14) of a fifth embodiment in accordance with the present invention; and

Figures 16 to 18 show end, side and top views of a sixth embodiment of the present invention; and

Figures 19 and 20 show further embodiments of the present invention.

Referring to Figures 1 to 4, a first embodiment in accordance with the present invention includes a hand held divergent narrow wavelength light source 4 with a built in timer and ambient light detector. A single wavelength is used at any one time, preferably in the infrared spectrum. However, the effective wavelengths which may be covered by such a device extend from the visible spectrum to the infrared. In

another embodiment of the invention, two wavelengths are used, one that is visible and the other that is invisible, particularly in the case where the optimal wavelength is in the infrared.

Light source 4 includes an elongate, rectangular cross-section hollow body with one end 1 being transparent to light. The light source includes an array of light emitting diodes 2 mounted close to transparent end 1. Power is delivered to devices 2 by means of batteries 3 located within the body 4.

The light source is provided with two On/Off switches 5 which may be actuated to initiate the operation of the internal electronics. Both buttons 5 have to be pressed simultaneously in order to operate the device correctly, thereby preventing inadvertent use of the device. Close to the end opposite transparent end 1 is a utility hole 6 which allows the light source to be hung up or attached to another article such as a bunch of keys.

The light source is provided with control electronics which limit the time that the light source is on and then automatically switches off the light source. The control electronics monitor the ambient light and, in the event that the ambient light is of an intensity that would interfere with the therapeutic effect of the light source, an alarm buzzer (not shown) sounds. The light emitting devices 2 and their location and arrangement within the light source are such that the light emitted from the light source is in the form of a divergent light beam. Flange 8 restricts the ambient light incident on the area whilst being treated.

Referring to Figures 5 to 7 of the accompanying drawings, a second embodiment in accordance with the present invention is constructed and shaped so as to be suitable for the delivery of photons to a human or animal appendage. Such devices may be portable and for use by those people who wish to have their own self-contained and battery operated devices. Generally, however, these devices are for use in medical clinics.

In this case the light source includes a hollow cylindrical body 3 having a flange 3a at one end. Light emitting devices 4 are arranged within the flange so that light emitted therefrom will pass through a transparent end flange wall in a direction away from the body of the light source. Further light emitting devices 4 are arranged to extend axially and peripherally along the length of the hollow cylinder of the body 3. These devices are mounted so that light emitted therefrom is directed radially inwardly through the internal transparent wall of the body 3.

During use the human or animal appendage may be located within the hollow body 3 to receive light emitted therefrom.

Control electronics 5 limit the time and hence the dose of photons to the affected site and automatically switch off the light source at the end of the period of irradiation.

Control electronics 5 also monitor the ambient light and sound alarm (not shown) should the ambient light exceed the threshold level.

Referring to Figures 8 to 10 of the accompanying drawings, a third embodiment in accordance with the present invention is in the form of a multi-panel narrow wavelength light source. In this case, a plurality of panels 3 are mounted in a side by side relationship on hinges 7 which, in turn, are connected to a stand 9 by means of arms 8 and 10. The arrangement is such that the panels can move relative to each other and the stand can be adjusted to alter the direction of illumination. The stand either extends from the floor or is attached to a chair or bed.

The front wall of each panel 3 is transparent and, mounted below the front wall, is an array of light emitting devices 4.

As with the earlier above described embodiments this embodiment of the invention includes control electronics to limit the time of the application of the radiation and to

monitor the ambient light and provide an alarm when the threshold value of the ambient light is exceeded.

Referring to Figures 11 to 13 of the drawings, a fourth embodiment in accordance with the present invention is in the form of a narrow wavelength light source with adjustable headgear.

The light source is, in use, located on the operator's head and includes two panels 1, 5 of light emitting devices, panels 1 being separated by an intervening notch 1a. These light panels 1 can be used either simultaneously or separately, there being provided a switch (not shown) to direct electrical power to one or both of panels 1.

The light panels 1 are held close to the eyes by adjustable control elements 2.

The light source is provided with control electronics 4 which limit the time of application of the photons to the affected site and also automatically switch off the light at the end of the application period. As before the control electronics monitor the ambient light and provide an alarm when the threshold level is exceeded.

Referring to Figures 14 and 15 of the accompanying drawings, a fifth embodiment of the present invention is in the form of a narrow or restricted bandwidth light source for delivery of photons to an orifice. In this case the body of the light source includes an elongate cylindrical portion 2 having at one end a flange 4 whose shape is indicated in Figures 14 and 15. At its other end, elongate portion 2 is hemispherical. Light emitting devices are located both in the elongate portion 2 and the flange 4 and this light source can be used to deliver photons to any orifice in the human/animal body, for instance, the vagina, anus and mouth. The light source may be provided in different sizes according to the size of the orifice into which it is to be inserted.

Control electronics limit the time of irradiation and monitor the ambient light, as with the previously described embodiments of the invention.

Figures 16 to 18 illustrate an oval application forming a sixth embodiment of the present invention. This is a very simple device with electrical or optical input at 2 and light emitting surfaces 1. The device may be placed in a patient's mouth for a period of, eg 4 minutes, to deliver light to the soft palate, aro and nasoparynx and larynx.

Figures 19 and 20 illustrate devices useful in the treatment of the common cold and acne.

The common cold is caused by a viral infection of the upper respiratory tract. The viral particles are almost exclusively found in the pharynx, sinuses and nasal passages.

The device is a light emitting apparatus which delivers a narrow bandwidth light which is of a wavelength that will penetrate the superficial skin and penetrate the underlying tissue to sufficient extent to generate a therapeutic effect.

The device in Fig 20 is flexible and is placed against the patient's face whilst he is lying supine. Notch 1 provides an aperture for the patient's eyes. Panel 2 provides treatment for the frontal sinuses. Panel 3 provides treatment for the maxillary sinuses and nose, and the intervening bridge 1a provides treatment for ethmoid sinuses and nose.

The device in Fig 19 is a flexible light emitting apparatus which is placed against the patient's neck so that the points 5 approximate the base of the patients ears. This apparatus delivers light for therapeutic effect to the patients larynx, oropharynx and laryngopharynx. Depression 4 fits underneath the patient's chin.

Devices for treating acne are as shown in Figures 19 and 20 and comprises several panels of variable shape and size. All the panels have a light emitting surface 2 and are flexible to enable the panel to follow the contour of the face and neck. Panels 6 and 7 (Figure 19) are applied to the inferior aspect of the chin and the neck respectively.

Panels in the Figure 20 device are applied to the face so that notch 1 enables the patient to see whilst being treated. Bridge 1a treats the bridge of the nose and extension 3 the cheeks. Notch 4 rests on the tip of the nose allowing the patient to breath comfortably during treatment. Panel 8 is used to treat the chin area and the area adjacent to the mouth.

Where the chest and/or back is involved a larger version of panel 6 would be used.

Due to the superficial nature of the pathology ambient light is of significance and an ambient light detector is utilised.

Treatment time is at most 10 minutes but typically 5 minutes.

It should be appreciated that two or more of the above-described devices can be used in conjunction with one another. An example is in the treatment of paediatric herpetic stomatitis where the device for delivery of light to an orifice could be used in conjunction with the multipanel device to ensure adequate delivery of the light system.

The application of light in the manner described appears to give the patient immediate (within 6 minutes) relief from any pain which is chemically mediated irrespective of the inflammatory condition causing it ie it gives pain relief in conditions other than those caused by viral infections. It does not affect the conduction of pain impulses as in local anaesthetics.

Examples of the invention will now be described with reference to the treatment of particular conditions.

Herpes

The light emitting surface was placed against the cold sore for at least 90 seconds, typically 4 minutes. The environmental conditions must be such that the ambient light to the cold sore must be decreased below acceptable levels. This can be achieved either by switching the light off or designing the device with a flange around the outside, diminishing the ultraviolet light to the area. Treatment is only once a day. One treatment may be all that is necessary however, in view of the fact that this also enhances wound regeneration and the wound regenerative effect only lasts 24 hours, daily treatments would improve clinical response. Various wavelengths were evaluated using a double blind control trial, Zovirax being given to the control patients. The average time for a control patient to heal was 9 days. The average time for patient to be treated with 660 nm light took 7.5 days. The average time for a patient to be treated with 1072nm light was 3 days if lesion was already present. However it was less than 12 hours if the patient only has a tingling sensation.

99.5% of patients abort their attack if they are treated within the tingling period using 1072nm light.

The number in the trial was 300.

Genital herpes

Again the applicator was required to follow the contours of the genitals and for a woman the cervix and posterior fornix was treated simultaneously with vagina and perineum. The treatment period is only 4 minutes. Due to the shape of the device, ambient light is excluded from the treatment area, and darkened room is not necessary.

Shingles

The light panel was applied to the area that is infected, for periods of 4 minutes. If the panel is applied to the actual skin surface and the panel is optically opaque it will occlude the ambient light from the area and hence allow treatment to proceed successfully. The only exception where a darkened room is essential is for the treatment of ophthalmic conditions when one cannot have the light emitting surface close to the eye because of the generation of heat. The generation of heat in association with ophthalmic conditions is contraindicated. A helmet was used with an ambient light detector with alarm so that the light can be delivered to the orbital region. Again the treatment period was 4 minutes. Generally ophthalmic conditions are treated on a daily basis. However, ophthalmic herpes can be treated once every three days to achieve a positive result.

The common cold

The patient was reclined on a bed, preferably in subdued lighting, but this is not essential. The device was placed against the skin ensuring that the frontal, ethmoidal and maxillary sinuses are covered. Another panel was placed again the neck, ensuring that the device goes as high as the angle of the jaw to enable treatment of the pharynx and larynx areas. The treatment cycle is at least 4 minutes. After that has been completed an oral device was used which is very similar to the vaginal applicator without the flange.. The device was inserted into the patient's mouth. The treatment period was again for 4 minutes. This applicator has a disposable outer skin, which is changed with each patient. The applicator will treat the soft palate and the back of the oral pharynx and the top of the nasopharynx where the surface applicator would not achieve acceptable penetration levels. Using this protocol alleviation of the pain associated with pharyngitis was achieved immediately, ie within 90 seconds, and the symptoms associated with oral pharyngitis have been alleviated within six hours.

Acne

Using the same applicator adolescent acne can be treated by the simple addition of a chin extension. The treatment time is 4 minutes. Ambient light is important but not in as much as the applicator will have an opaque surface so therefore it will be sheer proximity to the skin reduce ambient light to the skin. Applications should initially be every two to three days and maintenance would be perhaps once a week.

Musculoskeletal disorders

Treatment of musculoskeletal disorders such as tennis elbow gout, muscle injuries and knee injuries. The application time again is only 4 minutes. The light is directed over the affected area and gentle pressure is applied. Once the treatment is complete the patient feels immediate pain relief and improved joint movement. Muscle stiffness is greatly improved. This is a distinct advantage in the treatment of gout since this can be an extremely painful condition. The treatment could be repeated after 24 hours. Generally speaking treating prior the 24 hours is not indicated as there is no additional clinical benefit.

Post-operative wounds

24 hours after an operation, a 4 minute treatment period reduces pain for 6-8 hours and this was repeated three to four times a day to enhance would healing. The treatment may be used on a daily basis with or without the pain for post-operative wounds.

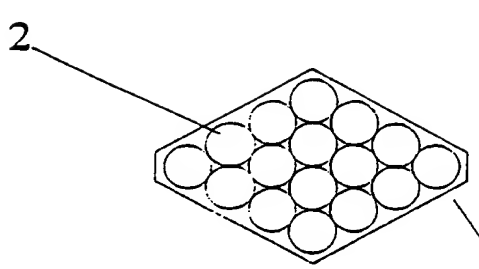
Rheumatoid arthritis

The painful areas are treated in a device which comprises one fixed panel in which the hands are placed on and a flexi panel which is placed over the top of the hands applying gentle pressure to aid additional penetration of the skin. The treatment time is 4 minutes. Ambient light does not appear to be a significant factor in the treatment of rheumatoid arthritis. Part of the treatment protocol can also be in the treatment of thymus, liver and regional lymph nodes, which are all associated with antigen recognition. Again treatment time is 4 minutes. the thymus, lymph nodes, liver and

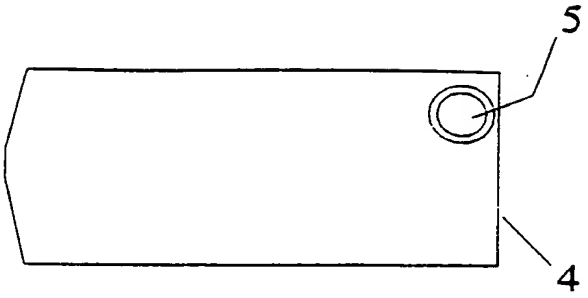
spleen may be treated once a week, whereas the hands may be treated initially once a week. However, during an acute exacerbation they can be treated daily. If treated more than once daily there appears to be no advantage.

Malignancy

The area of the tumour is treated together with treatment to the antigen recognition centres such as thymus, spleen, liver and lymph nodes. Daily whole body treatments may be carried out.



Front View
Fig 4



Side View
Fig 2

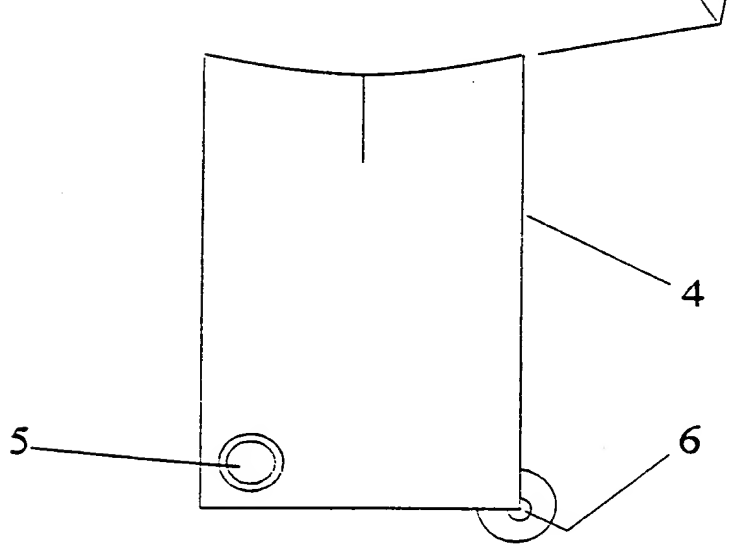


Fig 3 Underview

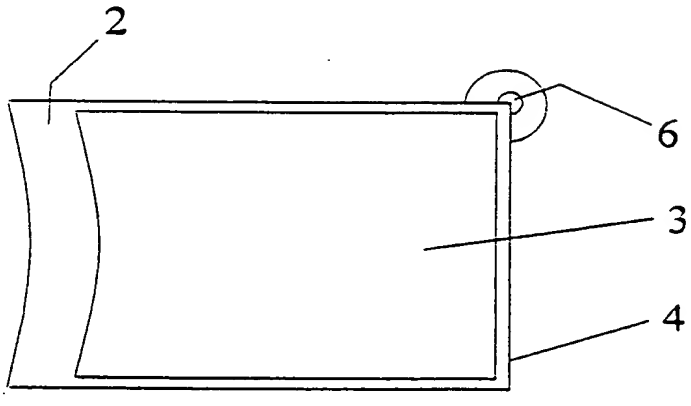


Fig 1 View with Cover Removed

PCT/GB 98/03073 - 12 OCT '98

HARRISON GODDARD FOOTE - 9727441.9